

AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO S. 1881
OFFERED BY MR. GREENWOOD

Strike all after the enacting clause and insert the following:

1 SECTION 1. SHORT TITLE.

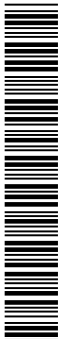
2 This Act may be cited as the “Medical Devices Tech-
3 nical Corrections Act”.

4 SEC. 2. TECHNICAL CORRECTIONS REGARDING PUBLIC
5 LAW 107-250.

6 (a) TITLE I; FEES RELATING TO MEDICAL DE-
7 VICES.—Part 3 of subchapter C of chapter VII of the Fed-
8 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379i et
9 seq.), as added by section 102 of Public Law 107-250
10 (116 Stat. 1589), is amended—

11 (1) in section 737—

12 (A) in paragraph (4)(B), by striking “and
13 for which clinical data are generally necessary
14 to provide a reasonable assurance of safety and
15 effectiveness” and inserting “and for which sub-
16 stantial clinical data are necessary to provide a
17 reasonable assurance of safety and effective-
18 ness”;



1 (B) in paragraph (4)(D), by striking
2 “manufacturing,”;

3 (C) in paragraph (5)(J), by striking “a
4 premarket application” and all that follows and
5 inserting “a premarket application or pre-
6 market report under section 515 or a pre-
7 market application under section 351 of the
8 Public Health Service Act.”; and

9 (D) in paragraph (8), by striking “The
10 term ‘affiliate’ means a business entity that has
11 a relationship with a second business entity”
12 and inserting “The term ‘affiliate’ means a
13 business entity that has a relationship with a
14 second business entity (whether domestic or
15 international)”; and

16 (2) in section 738—

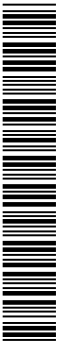
17 (A) in subsection (a)(1)—

18 (i) in subparagraph (A)—

19 (I) in the matter preceding clause

20 (i) by striking “subsection (d),” and
21 inserting “subsections (d) and (e),”;

22 (II) in clause (iv), by striking
23 “clause (i),” and all that follows and
24 inserting “clause (i).”; and



1 (III) in clause (vii), by striking
2 “clause (i),” and all that follows and
3 inserting “clause (i), subject to any
4 adjustment under subsection
5 (e)(2)(C)(ii).”; and

6 (ii) in subparagraph (D), in each of
7 clauses (i) and (ii), by striking “applica-
8 tion” and inserting “application, report,”;
9 (B) in subsection (d)(2)(B), beginning in
10 the second sentence, by striking “firms. which
11 show” and inserting “firms, which show”;

12 (C) in subsection (e)—

13 (i) in paragraph (1), by striking
14 “Where” and inserting “For fiscal year
15 2004 and each subsequent fiscal year,
16 where”; and

17 (ii) in paragraph (2)—

18 (I) in subparagraph (B), begin-
19 ning in the second sentence, by strik-
20 ing “firms. which show” and inserting
21 “firms, which show”; and

22 (II) in subparagraph (C)(i), by
23 striking “Where” and inserting “For
24 fiscal year 2004 and each subsequent
25 fiscal year, where”;



1 (D) in subsection (f), by striking “for fil-
2 ing”; and

3 (E) in subsection (h)(2)(B)—

4 (i) in clause (ii), by redesignating sub-
5 clauses (I) and (II) as items (aa) and (bb),
6 respectively;

7 (ii) by redesignating clauses (i) and
8 (ii) as subclauses (I) and (II), respectively;

9 (iii) by striking “The Secretary” and
10 inserting the following:

11 “(i) IN GENERAL.—The Secretary”;

12 and

13 (iv) by adding at the end the fol-
14 lowing:

15 “(ii) MORE THAN 5 PERCENT.—To
16 the extent such costs are more than 5 per-
17 cent below the specified level in subpara-
18 graph (A)(ii), fees may not be collected
19 under this section for that fiscal year.”.

20 (b) TITLE II; AMENDMENTS REGARDING REGULA-
21 TION OF MEDICAL DEVICES.—

22 (1) INSPECTIONS BY ACCREDITED PERSONS.—

23 Section 704(g) of the Federal Food, Drug, and Cos-
24 metic Act (21 U.S.C. 374(g)), as added by section



1 201 of Public Law 107–250 (116 Stat. 1602), is
2 amended—

3 (A) in paragraph (1), in the first sentence,
4 by striking “conducting inspections” and all
5 that follows and inserting “conducting inspec-
6 tions of establishments that manufacture, pre-
7 pare, propagate, compound, or process class II
8 or class III devices, which inspections are re-
9 quired under section 510(h) or are inspections
10 of such establishments required to register
11 under section 510(i).”;

12 (B) in paragraph (5)(B), in the first sen-
13 tence, by striking “or poses” and all that fol-
14 lows through the period and inserting “poses a
15 threat to public health, fails to act in a manner
16 that is consistent with the purposes of this sub-
17 section, or where the Secretary determines that
18 there is a financial conflict of interest in the re-
19 lationship between the accredited person and
20 the owner or operator of a device establishment
21 that the accredited person has inspected under
22 this subsection.”;

23 (C) in paragraph (6)(A)—

24 (i) in clause (i), by striking “of the es-
25 tablishment pursuant to subsection (h) or



1 (i) of section 510” and inserting “de-
2 scribed in paragraph (1)”;

3 (ii) in clause (ii)—

4 (I) in the matter preceding sub-
5 clause (I)—

6 (aa) by striking “each in-
7 spection” and inserting “inspec-
8 tions”; and

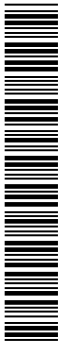
9 (bb) by inserting “during a
10 2-year period” after “person”;
11 and

12 (II) in subclause (I), by striking
13 “such a person” and inserting “an ac-
14 credited person”;

15 (iii) in clause (iii)—

16 (I) in the matter preceding sub-
17 clause (I), by striking “and the fol-
18 lowing additional conditions are met:”
19 and inserting “and 1 or both of the
20 following additional conditions are
21 met:”;

22 (II) in subclause (I), by striking
23 “accredited” and all that follows
24 through the period and inserting “(ac-
25 credited under paragraph (2) and



1 identified under clause (ii)(II)) as a
2 person authorized to conduct such in-
3 spections of device establishments.”;
4 and

5 (III) in subclause (II), by insert-
6 ing “or by a person accredited under
7 paragraph (2)” after “by the Sec-
8 retary”;

9 (iv) in clause (iv)(I)—

10 (I) in the first sentence—

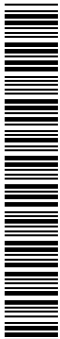
11 (aa) by striking “the two
12 immediately preceding inspec-
13 tions of the establishment” and
14 inserting “inspections of the es-
15 tablishment during the previous
16 4 years”; and

17 (bb) by inserting “section”
18 after “pursuant to”;

19 (II) in the third sentence—

20 (aa) by striking “the peti-
21 tion states a commercial reason
22 for the waiver;” and

23 (bb) by inserting “not” after
24 “the Secretary has not deter-



1 mined that the public health
2 would”; and

3 (III) in the fourth sentence, by
4 striking “granted until” and inserting
5 “granted or deemed to be granted
6 until”; and

7 (v) in clause (iv)(II)—

8 (I) by inserting “of a device es-
9 tablishment required to register” after
10 “to be conducted”; and

11 (II) by inserting “section” after
12 “pursuant to”;

13 (D) in paragraph (6)(B)(iii)—

14 (i) in the first sentence, by striking “,
15 and data otherwise describing whether the
16 establishment has consistently been in
17 compliance with sections 501 and 502 and
18 other” and inserting “and with other”; and

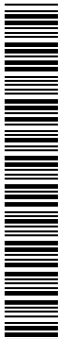
19 (ii) in the second sentence—

20 (I) by striking “inspections” and
21 inserting “inspectional findings”; and

22 (II) by inserting “relevant” after
23 “together with all other”;

24 (E) in paragraph (6)(B)(iv)—

25 (i) by inserting “(I)” after “(iv)”; and



1 (ii) by adding at the end the fol-
2 lowing:

3 “(II) If, during the two-year period following clear-
4 ance under subparagraph (A), the Secretary determines
5 that the device establishment is substantially not in com-
6 pliance with this Act, the Secretary may, after notice and
7 a written response, notify the establishment that the eligi-
8 bility of the establishment for the inspections by accred-
9 ited persons has been suspended.”;

10 (F) in paragraph (6)(C)(ii), by striking “in
11 accordance with section 510(h), or has not dur-
12 ing such period been inspected pursuant to sec-
13 tion 510(i), as applicable”;

14 (G) in paragraph (10)(B)(iii), by striking
15 “a reporting” and inserting “a report”; and

16 (H) in paragraph (12)—

17 (i) by striking subparagraph (A) and
18 inserting the following:

19 “(A) the number of inspections conducted by
20 accredited persons pursuant to this subsection and
21 the number of inspections conducted by Federal em-
22 ployees pursuant to section 510(h) and of device es-
23 tablishments required to register under section
24 510(i);”; and



1 (ii) in subparagraph (E), by striking
2 “obtained by the Secretary” and all that
3 follows and inserting “obtained by the Sec-
4 retary pursuant to inspections conducted
5 by Federal employees;”.

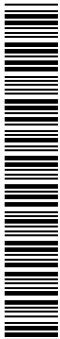
6 (2) OTHER CORRECTIONS.—

7 (A) PROHIBITED ACTS.—Section 301(gg)
8 of the Federal Food, Drug, and Cosmetic Act
9 (21 U.S.C. 331(gg)), as amended by section
10 201(d) of Public Law 107–250 (116 Stat.
11 1609), is amended to read as follows:

12 “(gg) The knowing failure to comply with paragraph
13 (7)(E) of section 704(g); the knowing inclusion by a per-
14 son accredited under paragraph (2) of such section of false
15 information in an inspection report under paragraph
16 (7)(A) of such section; or the knowing failure of such a
17 person to include material facts in such a report.”.

18 (B) ELECTRONIC LABELING.—Section
19 502(f) of the Federal Food, Drug, and Cos-
20 metic Act (21 U.S.C. 352(f)), as amended by
21 section 206 of Public Law 107–250 (116 Stat.
22 1613), is amended, in the last sentence—

23 (i) by inserting “or by a health care
24 professional and required labeling for in
25 vitro diagnostic devices intended for use by



1 health care professionals or in blood estab-
2 lishments” after “in health care facilities”;

3 (ii) by inserting a comma after
4 “means”;

5 (iii) by striking “requirements of law
6 and, that” and inserting “requirements of
7 law, and that”;

8 (iv) by striking “the manufacturer af-
9 fords health care facilities the opportunity”
10 and inserting “the manufacturer affords
11 such users the opportunity”; and

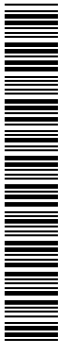
12 (v) by striking “the health care facil-
13 ity”.

14 (c) TITLE III; ADDITIONAL AMENDMENTS.—

15 (1) EFFECTIVE DATE.—Section 301(b) of Pub-
16 lic Law 107–250 (116 Stat. 1616), is amended by
17 striking “18 months” and inserting “36 months”.

18 (2) PREMARKET NOTIFICATION.—Section
19 510(o) of the Federal Food, Drug, and Cosmetic Act
20 (21 U.S.C. 360(o)), as added by section 302(b) of
21 Public Law 107–250 (116 Stat. 1616), is
22 amended—

23 (A) in paragraph (1)(B), by striking “,
24 adulterated” and inserting “or adulterated”;
25 and



1 (B) in paragraph (2)—

2 (i) in subparagraph (B), by striking “,
3 adulterated” and inserting “or adulter-
4 ated”; and

5 (ii) in subparagraph (E), by striking
6 “semicritical” and inserting “semi-crit-
7 ical”.

8 (d) MISCELLANEOUS CORRECTIONS.—

9 (1) CERTAIN AMENDMENTS TO SECTION 515.—

10 (A) IN GENERAL.—

11 (i) TECHNICAL CORRECTION.—Section
12 515(c) of the Federal Food, Drug, and
13 Cosmetic Act (21 U.S.C. 360e(c)), as
14 amended by sections 209 and 302(c)(2)(A)
15 of Public Law 107–250 (116 Stat. 1613,
16 1618), is amended by redesignating para-
17 graph (3) (as added by section 209 of such
18 Public Law) as paragraph (4).

19 (ii) MODULAR REVIEW.—Section
20 515(c)(4)(B) of the Federal Food, Drug,
21 and Cosmetic Act (21 U.S.C.
22 360e(c)(4)(B)) is amended by striking
23 “unless an issue of safety” and inserting
24 “unless a significant issue of safety”.



1 (B) CONFORMING AMENDMENT.—Section
2 210 of Public Law 107–250 (116 Stat. 1614)
3 is amended by striking “, as amended” and all
4 that follows through “by adding” and inserting
5 “is amended in paragraph (3), as redesignated
6 by section 302(c)(2)(A) of this Act, by adding”.

7 (2) CERTAIN AMENDMENTS TO SECTION 738.—

8 (A) IN GENERAL.—Section 738(a) of the
9 Federal Food, Drug, and Cosmetic Act (21
10 U.S.C. 379j(a)), as amended by subsection (a),
11 is amended—

12 (i) in the matter preceding paragraph

13 (1)—

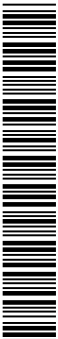
14 (I) by striking “(a) Types of
15 Fees.—Beginning on” and inserting
16 the following:

17 “(a) TYPES OF FEES.—

18 “(1) IN GENERAL.—Beginning on”; and

19 (II) by striking “this section as
20 follows:” and inserting “this section.”;
21 and

22 (ii) by striking “(1) Premarket appli-
23 cation,” and inserting the following: “(2)
24 Premarket application,”.



1 (B) CONFORMING AMENDMENTS.—Section
2 738 of the Federal Food, Drug, and Cosmetic
3 Act (21 U.S.C. 379j), as amended by subpara-
4 graph (A), is amended—

5 (i) in subsection (d)(1), in the last
6 sentence, by striking “subsection
7 (a)(1)(A)” and inserting “subsection
8 (a)(2)(A)”;

9 (ii) in subsection (e)(1), by striking
10 “subsection (a)(1)(A)(vii)” and inserting
11 “subsection (a)(2)(A)(vii)”;

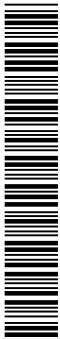
12 (iii) in subsection (e)(2)(C)—

13 (I) in each of clauses (i) and (ii),
14 by striking “subsection (a)(1)(A)(vii)”
15 and inserting “subsection
16 (a)(2)(A)(vii)”;

17 (II) in clause (ii), by striking
18 “subsection (a)(1)(A)(i)” and insert-
19 ing “subsection (a)(2)(A)(i)”;

20 (iv) in subsection (j), by striking
21 “subsection (a)(1)(D),” and inserting
22 “subsection (a)(2)(D),”.

23 (C) ADDITIONAL CONFORMING AMEND-
24 MENT.—Section 102(b)(1) of Public Law 107–
25 250 (116 Stat. 1600) is amended, in the matter



1 preceding subparagraph (A), by striking “sec-
2 tion 738(a)(1)(A)(ii)” and inserting “section
3 738(a)(2)(A)(ii)”.

4 (3) PUBLIC LAW 107–250.—Public Law 107–
5 250 is amended—

6 (A) in section 102(a) (116 Stat. 1589), by
7 striking “(21 U.S.C. 379f et seq.)” and insert-
8 ing “(21 U.S.C. 379f et seq.)”;

9 (B) in section 102(b) (116 Stat. 1600)—
10 (i) by striking paragraph (2);
11 (ii) in paragraph (1), by redesignating
12 subparagraphs (A) and (B) as paragraphs
13 (1) and (2), respectively; and
14 (iii) by striking:

15 “(b) FEE EXEMPTION FOR CERTAIN ENTITIES SUB-
16 MITTING PREMARKET REPORTS.—

17 “(1) IN GENERAL.—A person submitting a pre-
18 market report” and inserting:

19 “(b) FEE EXEMPTION FOR CERTAIN ENTITIES SUB-
20 MITTING PREMARKET REPORTS.—A person submitting a
21 premarket report”; and

22 (C) in section 212(b)(2) (116 Stat. 1614),
23 by striking “, such as phase IV trials,”.



1 **SEC. 3. REPORT ON BARRIERS TO AVAILABILITY OF DE-**
2 **VICES INTENDED FOR CHILDREN.**

3 Not later than 180 days after the date of enactment
4 of this Act, the Secretary of Health and Human Services
5 shall submit to the Committee on Health, Education,
6 Labor, and Pensions of the Senate and the Committee on
7 Energy and Commerce of the House of Representatives
8 a report on the barriers to the availability of devices in-
9 tended for the treatment or diagnosis of diseases and con-
10 ditions that affect children. The report shall include any
11 recommendations of the Secretary of Health and Human
12 Services for changes to existing statutory authority, regu-
13 lations, or agency policy or practice to encourage the in-
14 vention and development of such devices.

